Definitions

Alternate (or additional) Contact for Principal Investigator: This individual will be the secondary point of contact for the project.

Authorizing Contract Signatory: Authorized signatory on behalf of primary employer, if required by primary employer (e.g., University of Iowa Division of Sponsored Programs)

Confidential Data: Datasets that contain single or individual health events/records AND fields with content that directly identifies a person, such as name, address or social security number (SSN).

Data Owner: The individual who is in the position that is responsible for the dataset, as designated by the director or director's designee or as indicated by statute. The data owner may authorize or deny access to certain data within IDPH, and is responsible for accuracy, integrity and timeliness.

IDPH Identified Individuals: All individuals for whom IDPH data contains any of their contact information.

Implied Confidential Data: Datasets that contain single or individual events AND any fields with content that may indirectly lead to the identification of a person. The data contains demographic and other detailed information that could lead to the identification of a person, but does not contain direct identifiers, such as name or SSN.

Intended Start Date: This date refers to the anticipated beginning of the research project. This does not refer to the application process.

Intended Completion Date: This date refers to the anticipated end of the research project or the end of the current period of funding, whichever occurs first. The date does not refer to the application process or IDPH Research Agreement (RA). An explicit date or year is required. The entry "ongoing" is not an acceptable response for intended completion date.

Non-Confidential Data: Datasets that may contain single or individual events/records, but that do not contain any fields with content that may directly or indirectly identify a person. Non-confidential data would also include aggregated data.

Potential Subjects: The IDPH identified individuals selected by the P.I. for involvement in the research study.

Principal Investigator (PI): The individual responsible for the management of the research. The PI is the point of contact for all communication related to the review of the application and is also responsible for individuals who are authorized to access data received through the RA.

Please attach a brief biosketch describing professional accomplishments and qualifications. The biosketch should be no more than one page in length.

The mailing address provided by the principal investigator will be used to send one of two copies of the RA after acceptance of the application. The other copy will be sent to the authorizing contract

signatory. This mailing address will be entered by IDPH on page 5 of the RA after acceptance of the application.

The Grantor organization/institution is name of the entity affiliated with the project.

Publication: Any release or display of data in a publically accessible form is considered publication. This includes papers, posters, presentations, and/or public release.

Renewal Applications: The RA number for the original application should be included. The RA number will not change after acceptance of renewal application. The date of expiration of the most recent RA should be included. Please note, if the project is ongoing, then the renewal application should be submitted at least 60 days prior to the date of expiration. Otherwise the data will need to be destroyed in compliance with IDPH data destruction guidelines.

Research: A systematic investigation designed primarily to develop or contribute to scientific, medical, public health or psychosocial disciplines and generalized knowledge and not for private gain.

Research Agreement (RA): A legal contract between IDPH and any external entity (including other departments within state government) where IDPH agrees to release specific variables within a dataset that includes parameters of time and geography as requested in a research application. The receiving entity intends to use the requested dataset for the purpose of research and is bound by the confidentiality requirements in the RA.

Research Agreement Number (RA#): The RA# is given by IDPH after submission of the application. Each number is unique to the individual application. The RA# should be included in all documents and correspondence related to the application. Correspondence and other documents will not be accepted without the RA#.

Research and Ethics Review Committee (RERC): A committee outlined in IDPH policy #AD 07-12-004 responsible for reviewing all internal and external requests for IDPH data.

Researcher: Any individual associated with the project that will be working with the PI and have access to IDPH data. This individual(s) must sign the *Additional Signature(s)* page of the RA.

Procedure

1. Overview of the Project

Provide a brief summary or abstract of your project.

2. Study Type

Indicate the specific study type of the project. Please explain if the project is a single or multiple study types. Nested studies or multiple study types may require separate applications.

If this project is directly associated with any other ongoing or purposed studies that use IDPH data, then separate applications must be submitted for each project. Projects are considered directly associated if the same original dataset is used for multiple unrelated study aims or goals.

3. Hypothesis

Briefly describe the purpose of the project, and include the specific aims or goals. The aims and goals described must be realistic and cannot exceed 500 words.

4. Study Methods

The study methods should be clearly and completely described and should include legal and ethical considerations within the study design.

5. Public Health Importance

Describe how knowledge gained from this research will contribute to the understanding of health conditions or to an issue related to public health and is of intrinsic value to the people of Iowa.

6. Publication

Any release or display of data in a publically accessible form is considered publication. Review and approval of the results by IDPH is required prior to submission for publication. Even if the decision to publish the results of the study is made after the approval of the application and/or expiration date of the agreement, review and approval of the intended publication from IDPH is still required.

This is in accordance with the RA:

"If the Researcher is associated with an Iowa regent institution, the Researcher agrees to comply with the conditions regarding publications and presentations contained in Section 8(b) "I" of the General Conditions for Contracts with State Universities, effective January 1, 2013. If the Researcher is not associated with an Iowa regent institution, the Researcher agrees to provide a copy of the proposed publication to IDPH at least thirty (30) days in advance of the proposed dissemination date. The publication shall not be published in any format without the prior written consent of IDPH."

7. Contact with Individual Subjects

If contact with individual subjects and/or families is intended in this project and IDPH data are used to establish contact, then the following guidelines must be followed in accordance with the RA:

a. Attach all documentation for contact protocols, including contact letters and/or scripts, and the informed consent form.

b. The P.I. shall provide the RERC with a detailed description of how the P.I. intends to make contact with potential subjects and conduct subsequent follow-up. Initial contact with potential subjects shall be through the issuance of a joint notification letter from the P.I. and IDPH.

c. The P.I. will be responsible for writing the notification letter and performing mailings to potential subjects. Questions from potential subjects about the research project will be referred to the P.I.

d. A potential subject may choose to opt out of the study (verbally or in writing) at any time, and at that point attempts to enroll the person shall cease.

e. If approved by the RERC, IDPH will release identifiers or data elements needed for the purpose of contacting the identified individuals.

f. A list of study participants shall be maintained by the P.I. as confidential in accordance with the RA and shall be available for review by IDPH.

8. Institutional Review Board (IRB)

IDPH cannot give final approval of the project/study without IRB committee approval or exemption. All documents related to IRB committee approval are required in the research application, including the IRB application and approval letter. If the IRB application is more than 20 pages in length, then an additional brief synopsis is requested.

If the IRB application has been submitted but approval has not yet been given, then the anticipated date of approval is requested. If an anticipated date of approval for the IRB application is unknown, then the space should be left blank.

If project does not have an IRB expiration date, then provide the date needed for IRB annual review or renewal. This date of expiration may be the same as the project end date.

Exemption must be received from one of three sources: state statute, IRB committee, or Institution's Human Subjects Office. Exemption by state statute must be listed and specified as to which statutes apply. In the case of exemption by an IRB committee, the IRB committee determines that the study does not meet the regulatory definition of human subjects research and does not require review. If an IRB committee determines the project is exempt, written approval of exemption from that committee must be submitted. If an Institution's Human Subjects Office determines the project exempt, then the Determination Document must be submitted.

9. Data for Request

Dataset: Any collection of data fields and records.

a. Datasets: If desired dataset does not appear on partial list within the application, please contact RERC@idph.iowa.gov for more options.

Date Range: A date range must be selected for the requested dataset. The format for entering the date range is mm/yyyy. Note: not all datasets may be available for the indicated date range.

b. Variables: Please contact RERC@idph.iowa.gov for the dataset data dictionary if needed to determine requested variables.

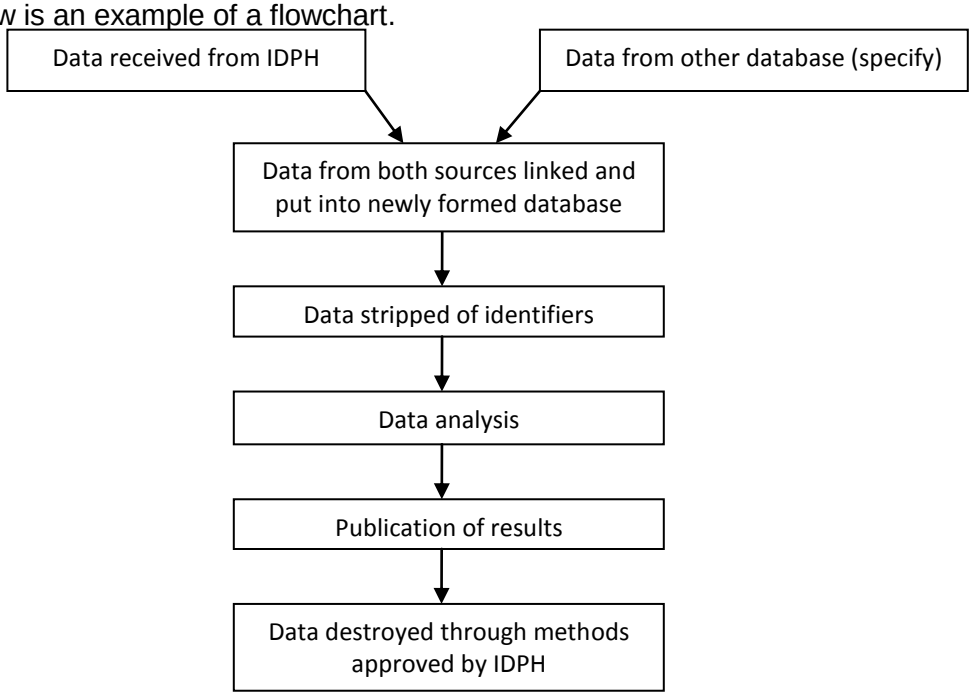
c. Geographic Area: Select all that apply. A geographical area within Iowa must be selected for the requested data.

10. Data Linkage

IDPH defines data linkage as the use of data from any other data source for comparison purposes, the creation of a combined database, matching, or extraction. This includes the use of a geographical area in comparison or matching. This does not include calculation of rates such as standardization and age-adjusted rates. Linkage is not limited to electronic databases. A selection of "no linkage" is not common.

The flowchart should be a visual representation of the use of data throughout the project. It should indicate if and where confidential identifiers are removed from the research file and indicate where in the process the researcher(s) will receive the data file. In some instances confidential identifiers may be used to link data by data owners/stewards before the researcher receives the data file.

Below is an example of a flowchart.



11. Data Format

The formats listed in the application are the only formats currently approved by IDPH. If "other" is selected, then please specify and provide a justification.

File transfer between all RA signatories must follow *IDPH's Security Rules for Media.* General fax, email, and cloud services are not approved forms of file transfer.

The cost for each format varies.

1. For a hard copy certificate (e.g., birth or death certificate) requested from the Bureau of Health Statistics, Vital Records requires a fee of $20 which is collected to cover the costs of conducting the search of our records and making a copy.
2. For electronic Vital Records data files, there is an initial $100 set up fee to cover the costs of creating a program to retrieve the data requested. Additionally, there is an additional fee of $1 for the disk or CD, and a $.30 per record fee. When a cost determination is made of the total cost, the P.I. will be notified. Upon receipt of payment the data will be released to the P.I.

Data Format for Electronic Data Files	Fee
Programming (including extraction)	$60.00/hour
Disk/CD	$1.00
Per Record	$0.30

3. For the fee schedules of other datasets, please email RERC@idph.iowa.gov.

12. Data Storage

The data storage methods listed in the application are the only data storage methods currently approved by IDPH. This list does not include cloud services and personal devices. Cloud services and personal devices are not acceptable storage methods for IDPH data. Any inquiries into other methods of data storage must be approved by the RERC and IDPH Information Management. This may result in delayed approval of the application.

The measures taken to ensure the security of all IDPH data must be described. The measures taken must be in compliance with *IDPH's Security Rules for Media*.

13. Confidentiality

The P.I. is responsible for maintaining the confidentiality of data received by IDPH. The P.I. is also responsible to ensure all other individuals (listed in #14) with access to IDPH data should operate in compliance with confidentiality standards set by IDPH. This includes any necessary training.

The data requested must be used for research purposes only. The data may not be transferred or reused by the P.I. without seeking explicit and additional approval of the RERC. The confidentiality standards of IDPH are further explained in the RA:

"The Researcher shall maintain the confidentiality of all IDPH Records. The Researcher shall not disclose any confidential information contained in the IDPH Records, including but not limited to names and other identifying information of persons who are the subject of such records, either during the period of this Agreement or hereafter. All identifiable and personal indicators shall be kept strictly confidential and shall not be used or released for any purpose.

The Researcher shall provide to IDPH a written description of its policies and procedures to safeguard confidential information. The Researcher shall designate one individual who shall remain the responsible authority in charge of all IDPH Records collected or used by the Researcher in connection with this Agreement.

Information from the IDPH Records shall not be used to establish contact with the named person or his/her family prior to written approval from IDPH. Prior to contacting the named person or his/her family, the Researcher shall execute IDPH's Protocol for contacting subjects.

The Researcher shall immediately report to IDPH any unauthorized disclosure of confidential information. Such disclosure shall be grounds for immediate termination of this Agreement."

14. Other Individuals with Access to Data

All individuals with access to aggregate data must be listed in the application. All individuals listed must sign the RA on the additional signature page. The P.I. is responsible for all violations of the RA for all co-signatories of the agreement under the supervision of the P.I. Any and all identifying data from IDPH is not to be shared in any public format. All individuals associated with this project, including the P.I., the authorizing contract signatory and all co-signatories of the RA must comply with *IDPH's Policy for the Disclosure of Confidential Public Health Records.*

a. The RA application must include the names of ALL individuals working with project that will have access to the IDPH data. This may include co-workers, students, and information technology specialists.

b. If the project has a designated data manager(s) who is responsible for the dataset, then provide their contact information here. This may include a registry staff member.

Penalties: The department has the authority to employ penalties for misuse of data. Penalties for violations of the RA may include, but are not limited to:

- Revocation of the RA to the PI and notice to the immediate supervisor of the violating PI.
- Notice of revocation of the RA to the entity's director.
- Immediate destruction of data confirmed by an independent third party, and may need to be approved by IDPH.
- Future requests by the violating PI and other implicated investigators may be denied.
- Additional sanctions as authorized by federal or state laws.

Destruction of Data: The *Confirmation of Destruction* form will be included with the formal approval letter after the project has been approved by the RERC and must be completed and returned to the RERC.

The destruction must be completed within 60 days of either:

When the project is complete

OR

The expiration date of the agreement

If the project is expected to last longer than the expiration date, the PI must apply for a renewal of the RA more than 60 days of the expiration date of the agreement. If a renewal is not approved by the RERC before the RA expiration date, the data must be destroyed in compliance with the Confirmation of Destruction. In accordance with the RA, "destruction shall be by means which render the IDPH Records unidentifiable and useless." The *Confirmation of Destruction* form should be sent to the RERC at RERC@idph.iowa.gov.